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Office of Pesticide Programs (7504C)
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One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

SUBJECT: SUBMISSION UNDER FIFRA SECTION 6(a)(2) CONCERNING THE ACTIVE INGREDIENT TRINEXAPAC-ETHYL, EPA REGISTRATION No. 100-727

In accordance with EPA's current interpretation of the reporting requirements of Section 6(a)(2) of FIFRA, Syngenta Crop Protection, LLC wishes to bring to your attention information from the *study "Trinexapac-Ethyl Technical: Local Lymph Node Assay in the Mouse"*. This non-guideline study was completed in support of the European re-evaluation to address the toxicological relevance of five Trinexapac-ethyl Technical impurities for skin sensitization and to support the EU Annex I renewal of Trinexapac-Ethyl Technical (designated as CGA163935D within Syngenta). This is the same technical currently registered in the US.

In this study, a sample of Trinexapac-ethyl Technical was fortified with five impurities [redacted] to the maximum levels designated on the Confidential Statement of Formulation (CSF142/4). This fortified sample was tested to determine whether these five impurities, when present at their maximum concentrations listed in the existing technical specification, resulted in a change in skin sensitization potential. The same Technical sample, without fortification, was negative in a previously conducted LLNA. When tested as a single substance, [redacted] tested positive as a skin sensitizer and the other four impurities had structural alerts (DEREK analysis) for potential skin sensitization.

A comparison of the impurity levels of the fortified Technical material and the unfortified Technical material is provided for reference in the confidential attachment to this letter, which should be treated as Confidential Business Information (CBI).

A sample of Trinexapac-ethyl Technical (CGA163935D), fortified with the five impurities previously discussed, was tested in a local lymph node assay (LLNA) as follows. The

vehicle used was 1% pluronic in distilled water. Treatment of mice with 25%, 50% and 100% of fortified Trinexapac-ethyl Technical resulted in stimulation index values of 1.57, 1.23 and 3.18, respectively. Based on the results of this study with the fortified technical material, fortified Trinexapac-ethyl Technical is considered to be a contact dermal sensitizer in the LLNA. The EC3 value calculated for the test substance was 95.4%, resulting in classification as a weak sensitizer.

Please contact me by email (matt.flanery@syngenta.com) or call me at 336-632-5688 if you have any questions regarding this submission.

Sincerely,

Matthew C. Flanery

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Enclosure (1): Confidential Attachment